

Serial No. 09/954,737
Docket No. GC634-2

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FROM: Carol See for Kamrin MacKnight,
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DATE: 22 August 2003

NUMBER OF PAGES TO FOLLOW: 8 SENT BY: cas

RE: Serial No. 09/954,737, Docket No. GC634-2

**Attachments: Transmittal Letter (1 page) in duplicate, and Response to
Restriction Requirement (6 pages).**

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I hereby certify that this correspondence is being sent by facsimile transmission in accordance with § 1.6(d) addressed to Art Unit 1636, Before Final Facsimile No. (703) 872-9306, Commissioner for Patents, Alexandria, VA 22313-1450 on the date shown below,

Date: August 22, 2003

By: Carol A. See

PATENT
Docket No. GC634-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
Bron *et al.*) Group Art Unit: 1636
Serial No.: 09/954,737) Examiner: Leffers, Gerald G., Jr.
Filed: September 17, 2001)
For: Twin-Arginine Translocation in *Bacillus*)

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Restriction Requirement dated August 7, 2003, enclosed please find the following document: Response to Restriction Requirement (6 pages).

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 07-1048 (Docket No. GC634-2). A duplicate of this paper is enclosed.

Respectfully submitted,

Date: August 22, 2003

Kamrin T. MacKnight
Kamrin T. MacKnight
Registration No. 38,230

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OFFICIAL

I hereby certify that this correspondence is being sent by facsimile transmission in accordance with § 1.6(d) addressed to Art Unit 1636, Before Final Facsimile No. (703) 872-9306, Commissioner for Patents, Alexandria, VA 22313-1450 on the date shown below.

Date: August 22, 2003

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PATENT
Docket No. GC634-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Bron *et al.*) Group Art Unit: 1636
Serial No.: 09/954,737) Examiner: Leffers, Gerald G., Jr.
Filed: September 17, 2001)
For: Twin-Arginine Translocation in *Bacillus*)

RESPONSE TO RESTRICTION REQUIREMENT MAILED AUGUST 7, 2003

Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

In response to the Restriction Requirement mailed August 7, 2003, Applicants respectfully request that the following amendments be made. A complete list of the Claims, including marked-up versions of the rewritten, added, and/or cancelled claims is provided below, beginning on page 2. None of the amendments to the Claims is intended to narrow the scope of any of the amended Claims within the meaning of *Festo*¹. The Remarks begin on page 4.

¹ *Festo Corp. v. Shoketsu Kogyo Kabushiki Co.*, No. 95-1066, 2000 WL 1753646 (Fed. Cir. Nov. 29, 2000).

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LIST OF CLAIMS, SHOWING THE STATUS OF EACH CLAIM

Underlining denotes added text while strikethrough denotes deleted text.

IN THE CLAIMS:

1. Claims 1-2. (cancelled)
3. (currently amended) A nucleic acid molecule comprising a first nucleotide sequence encoding a PhoD ~~or~~-LipA signal sequence operatively linked to a second nucleotide sequence encoding a heterologous polypeptide.
4. (currently amended) A recombinant expression vector comprising a first DNA sequence encoding a PhoD ~~or~~-LipA signal sequence operatively linked to a second DNA sequence encoding a heterologous polypeptide.
5. (currently amended) A host cell containing a recombinant expression vector comprising a first DNA sequence encoding a PhoD ~~or~~-LipA signal sequence operatively linked to a second DNA sequence encoding a heterologous polypeptide.
6. (original) The host cell of claim 5; wherein said polypeptide is not naturally associated with a secretion signal peptide.
7. (currently amended) A method for producing a polypeptide, comprising culturing a host cell containing a recombinant expression vector comprising a first DNA sequence encoding a PhoD ~~or~~-LipA signal sequence operatively linked to a

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second DNA sequence encoding a heterologous polypeptide such that the heterologous polypeptide is produced by the host cell.

8. (original) The method of claim 7, wherein the polypeptide is secreted by the host cell into a culture medium.

9. (original) The method of claim 8, further comprising recovering the polypeptide from the culture medium.

10. (currently amended) A method for producing a heterologous polypeptide in bacteria comprising:

- (a) culturing bacterial cells that (i) lack a functional *TatCy* gene and (ii) contain a recombinant expression vector comprising a first DNA sequence encoding a *PhoD* or *LipA* signal sequence operatively linked to a second DNA sequence encoding a heterologous polypeptide such that the heterologous polypeptide is produced by the cells; and
- (b) recovering the heterologous polypeptide from the periplasm or the culture medium.

11. (currently amended) A process for producing a heterologous polypeptide in bacteria comprising:

- (a) culturing bacterial cells that (i) overexpress one or more *B. subtilis* Tat system genes encoding membrane-bound components thereof and (ii) contain a recombinant expression vector comprising a first DNA sequence encoding a *PhoD* or *LipA* signal sequence operatively linked to a second DNA sequence encoding a heterologous polypeptide such that the heterologous polypeptide is produced by the cells; and
- (b) recovering the heterologous polypeptide from the periplasm or the culture medium.

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REMARKS

The present application was originally filed with 11 Claims. In the present Restriction Requirement, the Examiner has restricted the Claims into four Groups, with Claims 1-2, drawn to a chimeric polypeptide comprising a PhoD secretion signal derived from *B. subtilis* in Group I; Claims 1-2, drawn to a chimeric polypeptide comprising a LipA secretion signal derived from *B. subtilis* in Group II; Claims 3-11, drawn to nucleic acids encoding a chimeric polypeptide comprising a PhoD secretion signal derived from *B. subtilis*, cells comprising the same, and use thereof, in Group III; and Claims 3-11, drawn to nucleic acids encoding a chimeric polypeptide comprising a LipA secretion signal derived from *B. subtilis*, cells comprising the same, and use thereof, in Group 4.

The Examiner argues that the Groups represent separate and patentably distinct inventions because they have different functions, effects and modes of operation. While Applicants must respectfully traverse the restriction requirement, Applicants hereby elect the Claims in Group III (Claims 3-11, directed toward PhoD). Applicants reserve the right to file Divisional application(s) to pursue the presently cancelled Claims. Should the Examiner have any questions regarding this application, he is encouraged to call the undersigned.

Respectfully submitted,


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Date: August 22, 2003

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APPENDIX I

CLEAN VERSION OF THE ENTIRE SET OF PENDING CLAIMS AS AMENDED IN THIS COMMUNICATION

The following is a list of the Claims as they would appear following entry of this amendment.

3. (currently amended) A nucleic acid molecule comprising a first nucleotide sequence encoding a PhoD er-LipA signal sequence operatively linked to a second nucleotide sequence encoding a heterologous polypeptide.
4. (currently amended) A recombinant expression vector comprising a first DNA sequence encoding a PhoD er-LipA signal sequence operatively linked to a second DNA sequence encoding a heterologous polypeptide.
5. (currently amended) A host cell containing a recombinant expression vector comprising a first DNA sequence encoding a PhoD er-LipA signal sequence operatively linked to a second DNA sequence encoding a heterologous polypeptide.
6. (original) The host cell of claim 5, wherein said polypeptide is not naturally associated with a secretion signal peptide.
7. (currently amended) A method for producing a polypeptide, comprising culturing a host cell containing a recombinant expression vector comprising a first DNA sequence encoding a PhoD er-LipA signal sequence operatively linked to a second DNA sequence encoding a heterologous polypeptide such that the heterologous polypeptide is produced by the host cell.

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8. (original) The method of claim 7, wherein the polypeptide is secreted by the host cell into a culture medium.

9. (original) The method of claim 8, further comprising recovering the polypeptide from the culture medium.

10. (currently amended) A method for producing a heterologous polypeptide in bacteria comprising:

- (a) culturing bacterial cells that (i) lack a functional *TatCy* gene and (ii) contain a recombinant expression vector comprising a first DNA sequence encoding a *PhoD* or *LipA* signal sequence operatively linked to a second DNA sequence encoding a heterologous polypeptide such that the heterologous polypeptide is produced by the cells; and
- (b) recovering the heterologous polypeptide from the periplasm or the culture medium.

11. (currently amended) A process for producing a heterologous polypeptide in bacteria comprising:

- (a) culturing bacterial cells that (i) overexpress one or more *B. subtilis* Tat system genes encoding membrane-bound components thereof and (ii) contain a recombinant expression vector comprising a first DNA sequence encoding a *PhoD* or *LipA* signal sequence operatively linked to a second DNA sequence encoding a heterologous polypeptide such that the heterologous polypeptide is produced by the cells; and
- (b) recovering the heterologous polypeptide from the periplasm or the culture medium.